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Fonterra Co-operative Group Limited Submission on Department of Health and Human Services US Food and Drug Administration "Public Health Security and Bioterrorism Preparedness and Response Act of 2002"

# Docket No 02N-0278 Prior Notice of Imported Food - Section 307

## 4 April 2003

## **Fonterra Co-operative Group Ltd**

Fonterra Co-operative Group Ltd is a leading multinational dairy company, co-operatively owned by 13,000 New Zealand supplier shareholders. Exporting 95 percent of our shareholders' production, Fonterra is the world's largest exporter of dairy products, responsible for a third of international dairy trade across open borders.

Fonterra's global supply chain stretches from our shareholders' farms in New Zealand to customers and consumers in 140 countries. Collecting more than 13 billion litres of milk a year, we manufacture and market over 1.8 million tonnes of product annually, making us the world's leader in large scale milk procurement, processing and management, with some of the world's best known dairy brands.

#### **Submission**

#### 1 General Comments

- 1.1 Thank you for the opportunity to make comment.
- 1.2 This submission will be supported by a further submission from our Fonterra Regional Operating Company NZMP (USA).
- 1.3 Fonterra understands and supports the initiatives of the Government of the USA in establishing controls to protect the US food supply against the threat of bioterrorism.
- 1.4 However, Fonterra is concerned that the many counter measures being developed by the US Government to protect against bioterrorism, such as the Container Security Initiative, seems to be introducing a level of duplication which can only increase costs to both exporters and their US agents and customers. As an example, the information required under this

- section by the USFDA of prior notification of food shipments, is a duplication of that required by the US Customs under the Container Security Initiatives.
- 1.5 The voluntary Customs Trade Partnership Against Terrorism and Container Security also introduces the possibility of further duplication.
- 1.6 We strongly support the initiatives to work with US Customs to develop a joint database and recommend that all information provided to the various US authorities relating to the importation of food products be identified and included in this single information system. This would then enable exporters to supply all the required information once and would enhance the integrity of the information being used for the security assessment of imports.
- 1.7 However, Fonterra is disappointed that there is no indication in the current scope to include the provision of data through the electronic certification system that has been developed jointly by the New Zealand Food Safety Authority (NZFSA) and ourselves. We believe that the opportunity to provide the required information electronically again enhances information integrity, will increase efficiency and reduce costs both for the exporter and USFDA.
- 1.8 We are disappointed that the proposed rules do not recognise the existing statutory regulatory systems that are in place in New Zealand which dairy product producers such as ourselves are required to meet. The New Zealand Government through the NZFSA and in liaison with the dairy industry, operates a stringent control system for ensuring that all dairy products manufactured in New Zealand comply to domestic, international and importing country regulations. This control system based on NZFSA approved Product Safety Programmes, spans the total supply chain from farm production, milk collection, product manufacture, laboratory testing, product storage through to final container loading and transport. Final product certification is only provided on the evidence that all parts of the supply chain have complied with the stated regulatory standards.
- 1.9 This total supply chain approach to maintaining product integrity is subjected to regular audits from customers, independent third party agencies and foreign government regulatory authorities, including USFDA.
- 1.10 Fonterra strongly recommends that the New Zealand regulatory system is recognised as equivalent and therefore meets the provisions of Section 307.

### 2 Specific Comments

Who is authorised to summit the prior notice?

2.1 NZFSA in liaison with Fonterra is currently in the process of developing an electronic certification system that will contain all the information required under Section 307. Therefore there is the opportunity to provide this information via government-to-government electronic certification and thus remove the need for separate prior notice.

When must the Prior Notice be submitted?

2.2 The prior notice deadlines, particularly for airfreight, are unrealistic when considering the time differences between New Zealand and US airports and will undoubtedly lead to the Prior Notice details being incorrect and

- therefore requiring amendments, or possibly the product not arriving at all. In the case of sea freight, the Prior Notice could easily be lodged earlier than the allowable five days.
- 2.3 Fonterra request that the Prior Notice time periods be reviewed to reflect current business practicalities. We also request that we are not subjected to any penalties of product entry refused or unnecessary and costly delays due to events that are out of our control.
- 2.4 We are also unclear as to the treatment of product arriving that may not meet the Prior Notice criteria. Will the product be held and released upon provision of acceptable information or will it be required to be re-exported?
- 2.5 The harmonisation of both USFDA and US Customs information systems would be a major step towards increasing efficiency in this area by removing the need for Prior Notification.

What information must be submitted in a Prior Notice?

2.6 We are also concerned to note the number of proposed rule(s) that duplicate or are in conflict with those rules that are under US Customs responsibility. Therefore we question as to whether there is an intent and process for ensuring that both the duplication and conflict is removed and what will be the time period for this to occur?

What changes are allowed to a Prior Notice after it has been submitted?

2.7 While some flexibility has been allowed for under the rules to amend the Prior Notice, we are concerned that the changes are restricted to only being approved once and suggest that that any information on the Prior Notice can be changed with the submission time. As an example, the designated arrival time of ocean vessels at the Port of Discharge can often vary quite considerably and therefore a number of arrival time changes may be required.

If there are any queries relating to this submission, please contact Mike Willing, Compliance Manager, Fonterra Ingredients, on +64 4 471 8951 or email mike.willing@fonterra.com.

Yours sincerely

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